UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
CONGRESSIONAL AND
INTERGOVERNMENTAL
RELATIONS

The Honorable James Inhofe
Chairman
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

The Honorable Barbara Boxer
Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman and Ranking Member Boxer:

Thank you for your letter dated July 7, 2015, which included questions for the record following the hearing to consider the nomination of Thomas Burke to be Assistant Administrator in the Environmental Protection Agency's Office of Research and Development. Mr. Burke testified before the committee on June 11, 2015. Enclosed please find responses to those questions. If you have questions, you may contact me or your staff may call Christina J. Moody of my staff at (202) 564-0260, or email at moody.christina@epa.gov.

Sincerely,

Laura Vaught
Associate Administrator

Enclosure

Chairman Inhofe Questions for Thomas Burke, Nominee, Assistant Administrator, EPA Office of Research and Development

DUAL ROLE OF AA FOR ORD AND SCIENCE ADVISOR

The National Academy of Sciences previously reported that if the Assistant Administrator of the Office of Research and Development (ORD) is also the Science Advisor for the full agency it creates a conflict. Specifically, NAS concluded: "no single individual could reasonably be expected to direct a world-class research program in ORD while also trying to improve scientific practices and performance throughout the rest of the agency." Former Administrator Lisa Jackson took a step towards implementing this recommendation in 2009 by separating the offices. Even the Union of Concerned Scientists, the former employer of current EPA Scientific Integrity Official, Dr. Francesca Grifo, supported separating the offices, noting "This separation is a good thing, as a joint appointment makes it considerably more difficult for scientific integrity investigations to take place within ORD." During your June 11, 2015, nomination hearing, you stated that you planned, if confirmed, to serve a dual role.

Question 1: Doesn't this seem like a step in the wrong direction and counter to NAS recommendations?

Question 1a: As AA for ORD you will be managing nearly 1,800 employees, while the Science Advisor manages a team of about 30. How will you balance both roles?

Response:
After consultation with the NRC, the EPA Administrator and I believe that if the Assistant Administrator for the EPA's Office of Research and Development also served as the EPA Science Advisor that it would fulfill the recommendations of the NRC.

The dual role would provide the additional resources necessary to coordinate, plan, and execute science across the EPA; ensure there is a senior science official who could speak for the EPA on science issues; and help ensure strong scientific integrity in the agency's work. This individual would be very well positioned to help scientists across the EPA reach consensus on scientific issues.

Having served as the Deputy Assistant Administrator and the EPA Science Advisor since January of this year, it is clear to me that it is possible for the AA for ORD to direct the world-class research program in ORD and serve as the EPA Science Advisor. In fact, there is an important advantage to this model. ORD employs some of the nation's brightest scientists working on the most pressing environmental issues of the day. ORD research is well-aligned with the EPA's mission, and thus it produces science that informs the agency's decision-making needs. Because of this, the ORD AA has a top notch scientific staff to support him or her. Additionally, the ORD AA has the support of a stellar team of strong science managers in ORD. The EPA also has a built-in mechanism that would provide a check on any potential or perceived conflict of responsibility – the Science and Technology Policy Council (STPC) – a group of senior the EPA representatives that provide input on science and technology policy issues and ensures the EPA's science is well-coordinated.

If confirmed, I will draw on all of the available resources, and I feel confident that I will be able to balance both roles.

EPA RELIANCE ON OLD DATA

In 2004, the National Academy of Science cautioned against relying on decades old data for developing new National Ambient Air Quality Standards (NAAQS). Following your December 17, 2013, nomination hearing, you committed to "reviewing this issue and working to ensure that the Integrated Science Assessments that provide the foundation for NAAQS decisions reflect the best possible science." During your June 11, 2015, nomination hearing I asked what steps you have taken to ensure the agency is no longer relying on outdated science assessments, to which you said "there has been tremendous progress in doing that, to revisit and constantly upgrade the science."

Question 1: Specifically, what steps have you taken to end the use of this outdated data?

Question 1a: If no steps have been taken, why?

Question 1b: Don't you agree with the NAS recommendation? If not, why?

Response:
EPA's work to protect public health and the environment through programs such as decisions to retain or revise the National Ambient Air Quality Standards (NAAQS) is very important. I agree with the National Academy of Sciences (NAS) that NAAQS decisions must be based on the best possible science and am pleased to find that this is the case. After the 2004 NAS report, EPA revised the process to evaluate the science and has created Integrated Science Assessments (ISA) to provide the scientific basis for NAAQS decisions. ISAs have been completed for every NAAQS pollutant in the last several years, and in each instance there was extensive peer review by the independent Clean Air Scientific Advisory Committee of the EPA's Science Advisory Board and consideration of public comments. The quality of this review and the manner in which science informs NAAQS decisions has been lauded by the Administrative Conference of the United States, a Federal Advisory Committee (https://www.acus.gov/report/science-regulation-final-report). Additionally, the 2011 NRC report on EPA's draft IRIS assessment of formaldehyde complimented the revisions to the NAAQS documentation and review process. If confirmed, I look forward to working to ensure that the Integrated Science Assessments reflect full consideration of the best available science.

TRANSPARENCY

When asked during your June 11, 2015, nomination hearing about your efforts to make underlying data used to justify EPA regulations public, you said "there has been tremendous progress and I would be happy to provide more details on that."

Question 1: Please provide details on specifically what steps you have taken as Science Advisor to increase data access?

Question 1a: What additional steps do you plan to take to increase data access?

Response:
EPA is deeply committed to transparency. We are working rigorously to increase data access by building on and expanding the agency's existing efforts under the Open Government initiative (https://www.whitehouse.gov/Open/), including to make available the manuscripts and data supporting conclusions in EPA-funded publications.

An example of this Open Government effort that may be expanded would include the use of the Environmental Dataset Gateway (EDG) for storing and making data accessible. EDG is a gateway that anyone can use to search for publicly available data resources made available by the EPA's Program Offices, Regions and Laboratories. The EPA also now has in place the Enterprise Information Management Policy (EIMP; http://www2.epa.gov/open/enterprise-information-management-policy-eimp-cataloging-information-procedure) which ensures that information produced by, funded by, or received per regulated reporting and/or federal-wide requirements and subsequently held or cataloged in information management systems by the agency is easy to discover, understand, access, and reuse in a secure manner so it can be used with a broad array of applications and analytics to support the agency's mission and stakeholder needs.

Question 2: Independent peer review and independent verification of research results are key hallmarks of sound science. Do you agree that scientific confidence is increased when data is made available in a manner that allows for independent analysis and substantial reproduction of calculations and results by peer reviewers and other qualified scientists?

Response:
As I have stated previously, transparency and scientific integrity are very important to the agency's work. I understand that the EPA has taken appropriate and substantial steps to increase transparency and public access to information. However, it is essential to protect the privacy of individuals who have served as subjects in studies and their personal health information. If confirmed, I intend to continue the agency's ongoing efforts to ensure that scientific and technical information that is intended to inform or support agency decisions continues to be based on the best available science.

I under that internally the Integrated Risk Information System (IRIS) program no longer relies on definitions that are still publicly used (for example, the definition of the reference dose and the meaning of confidence values in IRIS), yet the EPA has never used any formal stakeholder or public or peer review process to implement these changes. Instead the EPA seems to be relying on a 2002 review received from the EPA's Risk Assessment Forum Technical Panel and appears to pick and choose which suggestions they will follow and which they will not implement.

Question 2a: Will you commit to engaging stakeholders before changes to critical definitions and methodologies in the NAAQS and IRIS program are made?

Response:
Stakeholder engagement is an important and informative part of the agency's work. The IRIS assessment development process provides multiple opportunities for stakeholder engagement, and the IRIS Program is convening bimonthly public science meetings to discuss IRIS assessments and related scientific issues. Likewise, there are multiple opportunities for stakeholder engagement in the NAAQS process. If confirmed, I will work to ensure appropriate stakeholder engagement occurs in the NAAQS and the IRIS Program.

PEER REVIEW

Question 1: Will you committ to more transparent procedures for determining what EPA documents are "highly influential scientific" documents pursuant to the Information Quality Act.

Response:
Yes, if confirmed, I will commit to more transparent procedures for determining what the EPA documents are "highly influential scientific" documents pursuant to the Information Quality Act.

GRANTS

Although the Shelby Amendment, otherwise known as the Data Access Act, provides for agency access to underlying data that is federally funded, there are instances in which EPA does not have full access to funded data.

Question 1: Will you commit to implementing provisions in grants and contracts that maintain rights to obtain data first produced under an award?

Response:
The EPA is committed to increased public access to the EPA-funded data supporting conclusions of peer-reviewed publications and is working diligently to strike the right balance between supporting the publics' right-to-know while ensuring that in its role as a regulatory agency, it provides the right level of protection for specific categories of scientific data. If confirmed, I will commit to working with others in the Agency to see what steps can be taken to increase public access to such data from grants and contracts.

IMPROVING RISK ASSESSMENTS

EPA's Risk Characterization Policy calls for the agency to develop and use multiple risk descriptors. The 2014 National Research Council IRIS review recommended the IRIS program develop central and lower-bound risk estimates.

Question 1: Per these recommendations, do you commit to ensuring the IRIS program present risk ranges – including low, central and upper-bound estimates?

Response:
The EPA is committed to further improving the IRIS program and is working to address the NRC's 2014 recommendations for IRIS. During my time at the agency, I have seen that the EPA takes the NRC's recommendations very seriously. If confirmed, I look forward to working with the IRIS program as they make further changes to address the NRC's recommendations and providing a more robust characterization of risk estimates.

Question 2: Certain substances-for which there may also be environmental exposure - are produced naturally in the body as a result of normal metabolism and physiology.
Do you agree that when ORD programs assess potential risks from such substances, it's critical to derive the range of potential risks arising from both sources-internal and environmental—and to communicate the degree to which these estimated risks from internal and external sources are plausible and realistic?

Response:
This is an important consideration in understanding and managing incremental risk from environmental exposure. Since there are many natural products of metabolism that may have toxic effects if they are out of balance, the fact that they are naturally produced does not make them "safe" at all doses.

Question 3: Consistent with the National Research Council 2011 Formaldehyde report, the NRC 2014 IRIS report recommended EPA improve its methods for study evaluation and integration. Do you commit to use clear criteria for judging quality of all key studies and integrate those studies based on their strengths and weaknesses?

Response:
Consistent with the NRC recommendations, the IRIS program is evaluating different approaches for systematically reviewing the scientific literature and evaluating individual studies, synthesizing evidence within a particular discipline, and integrating evidence across different disciplines to draw scientific conclusions. If confirmed, I will commit to working with the IRIS program to improve its methods for study evaluation and integration.

Question 4: Will you commit to ensuring that all draft and final assessments released by the IRIS program are consistent with the recommendations of the National Research Council Formaldehyde committee which recommended changes for all IRIS assessments, not just formaldehyde?

Response:
The IRIS Program has been implementing the recommendations using a phased approach, consistent with the advice of the National Research Council (NRC), making the most extensive changes to assessments that are in the earlier stages of assessment development. Additionally, in July 2013, the EPA announced enhancements to the IRIS Program that will improve the science quality of assessments, improve the productivity of the Program, and increase transparency. These changes are consistent with the NRC recommendations. If confirmed, I look forward to working with the National Center for Environmental Assessment as they continue to implement these enhancements in the IRIS program.

Question 5: Do you agree that standard protocols should be developed to enable all studies to be independently judged based on their quality, strength, and relevance regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?

Response:
The EPA's work to protect public health and the environment needs to be based on strong science. If confirmed, I will commit to ensuring that we use clear criteria for judging quality of all studies and will integrate these studies based on their scientifically determined strengths and weaknesses and not on authorship or funding source.

Question 6: Will you ensure that as part of the improvements in the IRIS program, the agency will move away from outdated default assumptions and instead start with an evaluation of the data and use modern knowledge of mode of action—how chemicals cause toxicity instead of defaults?

Question 6a: That is, will you commit to using relevant data over defaults in IRIS assessments?

Question 6b: To extent defaults are used, will you ensure EPA has clear criteria for determining when such defaults are justified in lieu of relevantt literature and data?

Response:
EPA's work to protect public health and the environment needs to be based on strong science. When the IRIS program assesses a chemical, they systematically review the relevant literature and look at all of the available scientific data – including data about a chemical's mode of action. Where sufficient scientific data are available, the EPA uses that information in its risk assessments. However, for many chemicals, we do not have sufficient scientific data to inform certain elements of assessing a chemical hazards – such as mode of action. In the absence of sufficient scientific data, the EPA generally uses public health protective and scientifically-based default positions in risk assessments. If confirmed, I will work to assure that the application of defaults is based upon strong, transparent science.

Question 7: Can you commit to developing a clearly articulated prioritization process for high priority IRIS assessments that benefits from, and is responsive to, engagement from all stakeholders? Will you ensure coordination with other EPA program offices?

Response:
The EPA has previously committed to the Government Accountability Office that it will better describe for internal and external stakeholders and the public the nomination and selection process for chemicals for IRIS toxicity assessments, including the rationale for not selecting nominated chemicals for the full IRIS assessment. Additionally, the IRIS Program works very closely with the EPA's program and regional offices in setting priorities, and there are multiple opportunities for the public to provide input into all elements of the IRIS Program. If confirmed, I commit to the development and release of a prioritized IRIS Agenda covering the next several years' effort.

Question 8: EPA finalized an IRIS assessment for TCE in 2011 that established a safety value based primarily on controversial findings from a single laboratory. At the time, the agency acknowledged the significant limitations of these studies, and indicated that addressing these limitations was a key research need for understanding potential health effects associated with TCE. What has the agency done to address this key research need since reaching its conclusion in 2011?

Question 8a: It is my understanding that the industry has volunteered to conduct such research – with the oversight of the federal agencies. Has EPA agreed to provide such oversight? If not, why?

Question 8b: I understand that Dr. Ken Olden has been a proponent of such joint projects. Do you agree with Dr. Olden's assessment? What steps has EPA to pursue joint projects?

Response:
While more research might be informative, the EPA concluded in 2011 that there was a sufficient basis for developing a reference concentration for TCE. This value was based on two endpoints: fetal heart malformations and immunotoxicity resulting from TCE exposure. The reference concentration of 2 ug/m^3 reflects both of those effects.

There are no significant uncertainties that have arisen since 2011 that would change the EPA's conclusions as to a chronic reference concentration or that were not considered prior to the release of the final assessment.

The EPA has not agreed to provide oversight of industry conducted research on TCE. While partnerships between research organizations can be valuable, at this time we are not pursuing a joint

TCE research project with industry. Also, scientific decisions are based on the full body of evidence, and it is not usual that one additional study would drive the evidence base.

Question 9: I have heard concerns about the application of EPA's new safety value to sites contaminated with TCE, particularly as it is related to vapor intrusion. Apparently, this can substantially increase the complexity and cost of investigating and remediating these sites. Given the limitations associated with the safety value established in 2011, is it appropriate to apply the value in such situations?

Question 9a: Shouldn't there be some discretion provided to the site manager in applying such an uncertain value?

Question 9b: What information is provided to the site manager about the uncertainty surrounding the value?

Response:
IRIS assessments, like TCE, are developed for use by agency risk managers in a variety of situations – including, in this case, vapor intrusion. The IRIS assessment, however, does not dictate how risk managers use scientific information in decision-making. In the case of sites subject to CERCLA or RCRA, the National Contingency Plan, relevant RCRA corrective action rules, and programmatic guidance address how site managers should consider a range of factors in making appropriate risk management decisions. In general, decisions to take action are based on site-specific circumstances. There are some limitations in the available data for determining a concentration below which TCE exposures are unlikely to cause the developmental effect of fetal heart defects. That uncertainty was described in the IRIS assessment and highlighted in the August 2014 OSWER memo. This information is available to site managers.

SCIENCE ADVISORY BOARD

Question 1: Based on your time on the SAB, to what extent did ORD use the SAB in the past? Since you have been at the EPA, how and how frequently has the agency used the SAB?

Question 1a: Do you think the SAB is not used enough?

Question 1b: To what extent has the SAB met ORD's information and review needs?

Response:
The SAB is a tremendous resource for the agency and the nation, and it is being used to provide guidance on our most challenging scientific issues. During my time as a member of the SAB (from FY2008 to FY2013), the Board prepared over 75 advisory reports to the EPA Administrator on topics ranging from the adequacy of the EPA risk assessments to approaches to setting water quality criteria and conducting economic analyses to peer reviews of state of the science reports. The SAB also prepared in-depth studies of the science related to reactive nitrogen and integrated science for decision making. To my knowledge, the SAB has responded to all agency requests for advice and peer review. The SAB has responded to all of ORD's review requests. In addition, I have initiated discussions with the EPA Science and Technology Policy Council (composed of senior leaders from across the agency) to ensure that the highest priority, cross-agency science questions are identified and that the agency takes full advantage of its SAB as a source of advice on those questions.

Question 2: **In the past ORD has asked the SAB for advice on its research programs, including human health risk, air, climate and energy, chemical safety, and water resources? Do you think there are areas within ORD that should have gone to the SAB for advice?**

Response:
Many of ORD's most complex and controversial scientific assessments—including assessments of chemicals prepared for the Integrated Risk Information System (IRIS) and state-of-the-science assessments on the impacts of mountaintop mining, connectivity of waters, and hydraulic fracturing—were sent to the SAB for review. The SAB Chemical Assessment Advisory Committee (CAAC) has recently been put in place to provide advice to the IRIS program on their assessments. In addition, the SAB recently met jointly with the ORD Board of Scientific Counselors to provide high-level strategic advice on the EPA's research directions and research plans. I will continue to seek SAB advice on ORD research directions and SAB peer review of high profile scientific work products.

Question 3: **Can you comment on the advantages and disadvantages of the process SAB uses to provide advice to the agency?**

Response:
The SAB operates under the provisions of the Federal Advisory Committee Act (FACA) and implementing regulations, which require that all SAB meetings be announced and open to the public and that all materials provided to the SAB are available to the public. In addition, agency policies encourage public nomination of experts to serve on the SAB and provide multiple opportunities for public input to SAB committees and panels.

The primary advantage of the SAB process is that it gives the EPA access to independent advice from non-EPA experts who are nationally renowned in their disciplines, and it does so in a transparent, public manner with opportunities for public input. Although the SAB strives for consensus advice, in cases where there is disagreement among Board members on scientific questions the SAB reports provide the range of scientific opinion.

There are tremendous advantages to the SAB process. A potential disadvantage to the SAB process, which complies with FACA and ethics regulations, is the time required to form ad hoc panels and to announce and hold public meetings for the purpose of developing SAB advice. If confirmed, I look forward to working with the Board to facilitate more nimble and timely reviews, especially for emerging issues that demand a timely response.

Question 4: **During your time on the SAB did it have an Executive Committee?**

Question 4a: **If it did, how often did it meet?**

Question 4a (i): **Did you ever meet with the Executive Committee?**

Question 4a (ii): **Did the Executive Committee ever meet with the EPA Administrator and engage in dialogue?**

Question 4b: **Some individuals have indicated that in the past when the SAB had an Executive Committe SAB was more effective and independent. Would you recommend that the SAB have an Executive Committee?**

Response:
During my service on the SAB, there was no Executive Committee. Prior to 2003, the SAB consisted of an Executive Committee (composed primarily of chairs of the Standing Committees) and a number of discipline-specific Standing Committees. The Executive Committee provided advice to the agency and reviewed and approved the work of the Standing Committees. In 2003, the SAB was restructured and the Executive Committee was replaced with a realigned Board that oversees the activities of a number of Standing Committees and ad hoc panels. A primary difference between the Executive Committee of old and the current Board is that the Board has a larger number of members and occasionally conducts strategic reviews on cross-cutting topics of interest to the EPA. A recent example of a Board-level activity is the 2012 report on Science Integration for Decision Making.

There is a long standing tradition for the EPA Administrators to meet with the SAB Executive Committee or Board and this tradition has been continued by Administrator McCarthy, who met with the SAB in December 2013 to discuss broad areas where the Board's advice could be helpful to the agency. I disagree with the notion that an Executive Committee would be more effective or independent than the current organization of the Board, which includes 45 expert scientists with a broad range of expertise, affiliation, and experience.

Question 5: In your proposed new role as Assistant Administrator for Research and Development, how do you plan to use the SAB?

Question 5a: Do you plan to review appointments to the SAB and its various committees?

Response:
The SAB Staff Office seeks public comments on the nominees and candidates willing to serve on the SAB and its committees. That public process allows anyone to provide input. This includes Congress, the public, constituent groups and the agency. I have and will continue to provide input as warranted on these important decisions.

Question 5b: Will you seek to ensure appropriate geographic diversity when potential SAB members are identified from the thousands of qualified scientists across the U.S.?

Response:
In making appointments to the SAB and its committees, the Administrator considers the needed balance of scientific and technical points of view, as well as diversity of perspectives (e.g., geographic, economic, social, cultural, educational and other considerations). Each SAB review has a unique set of needed expertise and perspectives and the SAB Staff Office works to understand those needs and to ensure that they are met when ad hoc panels are established.

Question 5c: The U.S. has many well-qualified scientists employed by academe, government and industry, yet most SAB members are from academic institutions on both coasts. What will you do to increase the participation of industry scientists and scientists from American heartland?

Response:
To some extent the SAB reflects the proportional makeup of the scientific community. However, the SAB's outreach efforts (i.e., recruiting efforts, webinars, and open door policy to meet with external organizations) have been successful in ensuring a greater diversity of members. For the current Chartered SAB members, approximately 32 percent have experience with industry / consulting and

13 percent have state /local or tribal experience. The current SAB hydraulic fracturing advisory panel has over 200 years of combined industry experience. With respect to geographic diversity, 11 of the 45 members currently serving on the Chartered SAB reside in the midwestern states (Iowa, Illinois, Indiana, Ohio, and Minnesota). The agency continues its efforts to increase participation in SAB reviews from all relevant scientific and technical communities.

HUMAN TESTING

In April 2014, the EPA Inspector General issued a report on EPA's human testing program, including several corrective actions. Notably, that EPA be fully transparent on the level of risk for pollutants exposed to human subjects. Earlier this week, news reports revealed EPA has not fully complied with the corrective actions.

Question 1: As EPA's Science Advisor, what steps have you taken to comply with these corrective actions?

Response:
All corrective actions have been implemented, per the completion memo dated 4/24/2015. In fact, we have gone beyond what the Office of Inspector General requested. While the recommendations were directed solely at enhancing the human studies that the EPA conducts at ORD's National Health and Environmental Effects Research Laboratory (NHEERL), many of the recommendations were applicable beyond NHEERL and are therefore being implemented agency-wide, where appropriate.

Question 1b: Do you think there a threshold below which there are no negative health effects for certain pollutants?

Response:
In order to answer this question, we must know both (a) the pollutant in question, and (b) whether the health effects mentioned refer to a large population or an individual. As an example for PM2.5, when the entire population of the U.S. is taken into account, numerous epidemiology studies have indicated there is no threshold below which adverse health effects do not occur in at least some people. There are some individuals in the population that are at such great risk (because of pre-existing disease, age, genetic makeup, etc) that they will experience an adverse health event at even very low concentrations of PM2.5. However, for most individuals, the risk from exposure to low concentrations of PM2.5 is very, very low. It is also important to distinguish between a single exposure to PM2.5 versus a lifetime of exposure. Just as smoking a single cigarette is not likely to cause an adverse event, compared with a lifetime of smoking, a single exposure to even high concentrations of PM2.5 is not likely to cause adverse health effects. Additionally, certain information about a chemical – such as its mode of action – can help inform whether or not a there is a threshold.

Question 1c: Do you believe human testing is justified? Is testing on children ever justified?

Response:
There's an important different between observational studies of populations and intentionally dosing humans with a pollutant. Scientists learn a lot from research in test tubes or animals, and from epidemiologic or observational studies on humans, which typically involve little interaction with subjects. However, these types of studies rely heavily on statistical inferences and assumptions, and

there are some things you can only learn by interacting directly with people, controlling variables and methods to allow firm conclusions to be drawn.

When EPA conducts studies with human subjects, we set—and meet—the highest safety and ethical standards.

The EPA is among 17 federal agencies that have adopted rules governing the protection of human subjects in research. The EPA's guidelines far exceed what is generally accepted and required by universities, industry, and other government agencies. For example, any of our research that involve human participants typically undergo more than eight separate levels of approval stages before any research is initiated. These include statistical and medical reviews of the study, reviews by an Institutional Review Board, Quality Assurance Officer review, and review by at least three other senior officials, whose approvals must be documented before a study can begin.

The EPA does not intentionally expose children to pollutants. However, the EPA has funded some important epidemiological studies that include children. These studies have provided critical information about children's exposures to pollutants, their susceptibilities, and the health effects that occur from the exposures. This research ultimately helps the EPA better understand how to protect children from the harmful effects of pollutants.

PETER PREUSS

Question1: Do you agree that Dr. Ken Olden is bringing much needed new leadership and transparency to the IRIS program?

Question 1a: Do you agree that the National Center for Environmental Assessment review (NCEA) previously operated behind closed doors where many stakeholders and peer reviewers did not understand NCEA's scientific approach?

Question 1a (i): Wasn't the previous NCEA Director Dr. Peter Preuss?

Question 1a (ii): Isn't it true you recently appointed him as one of your Deputy's in the Office of Science Advisor?

Question 1a (iii): Can you explain the reason for his appointment?

Response:
I agree that Dr. Ken Olden is an outstanding leader who has brought additional transparency, including multiple opportunities for stakeholder input, to the IRIS Program. Dr. Peter Preuss was a former director of the EPA's NCEA, but starting in 2010 he was ORD's Chief Innovation Officer. The EPA recently created a new position, the director of the Office of the Science Advisor, to more effectively support the agency's Science Advisor. Peter Preuss is the interim director, and we anticipate announcing the name of the new permanent director soon.

Senator Sessions Questions for Thomas Burke, Nominee, Assistant Administrator, EPA Office of Research and Development

During the April 2013 confirmation hearing for your boss (the EPA Administrator, Gina McCarthy), she promised the Environment and Public Works Committee under oath that she would "provide information . . . with respect to [her] responsibilities." However, instead of living up to her promise, the Administrator often directs others to respond to questions that are posed directly her.

For example, this past April, I and other members of the Committee wrote a letter to the Administrator regarding projected climate change impacts. Despite having committed to providing responses during this Committee's budget hearing for EPA, the Administrator directed Janet McCabe, the Acting Assistant Administrator for the Office of Air, to provide responses.

Question 1: If you are confirmed, will you personaly answer questions that are asked of you by members of this Committee?

Response:
If confirmed, I will commit to answering questions posed by SEPW to the best of my ability.

Question 2: The April 2015 letter asked straightforward questions related to whether projected climate impacts are actually occurring. Yet instead of reviewing and verifying the accuracy of climate projections which have served as the basis for the agency's regulatory policy and agenda, the Acting Assistant Administrator opined on future projections. For example, in response to a series of questions on global cyclone activity over the past century, the Acting Assistant Administrator wrote: "Anthropogenic climate change is . . . expected to contribute to a number of changes in extreme weather events... [T]ropical cyclone intensity is . . . expected to increase in the future, but the frequency of cyclones is likely to either decrease or remain unchanged." Do you agree that estimates of future climate impacts do not answer whether climate impacts projected and expected to occur in the past have proven accurate?

Response:
While this is not an area in which ORD plays a primary role, my understanding is that it is important to both consider how the climate is changing today, and how future changes will impact humans and the environment. Regarding the former, the EPA publishes a set of indicators describing trends related to the causes and effects of climate change. Focusing primarily on the U.S., this resource presents compelling evidence that many fundamental measures of observed climate are changing (see http://www.epa.gov/climatechange/science/indicators). The EPA's indicators consist of peer-reviewed, publicly-available data from a number of government agencies, academic institutions, and other organizations. The scientific community, including some work supported by the EPA, also considers how climate impacts may change in the future, building upon our understanding of what is happening today.

Question 3: I also asked in the letter whether the Administrator agreed that it has been nearly ten years since the last major hurricane struck the United States. The Acting Assistant Administrator's response did not answer this question. As the EPA's Science Advisor, please answer the following:

Question 3a: Was it appropriate for the Acting Assistant Administrator to refrain from confirming whether it has been nearly ten years since the last major hurricane struck the United States?

Question 3b: Does EPA have the institutional capability to review recent data on hurricane landfall and determine whether it has been nearly ten years since the last major hurricane struck the United States?

Response:
Again, while this is not an area where ORD plays a role, whether an individual storm event is determined to have met the criteria to be classified as a hurricane is a finding made by the National Oceanic and Atmospheric Administration (NOAA). It is my understanding that the EPA has the institutional ability to review data produced by NOAA, but does not produce original data regarding hurricanes. Staff at the EPA would defer to their expertise on this issue.

In general, it is difficult to draw conclusions about the number of major hurricane landfalls in a short period such as ten years. To illustrate this variability, there were seven major hurricane landfalls in the U.S. in the years 2004 and 2005, but none in the years that followed. Looking across multiple decades, the trend becomes clearer, which is why the Intergovernmental Panel on Climate Change came to the following conclusion in its 2013 Fifth Assessment Report: "it is virtually certain that the frequency and intensity of the strongest tropical cyclones in the North Atlantic has increased since the 1970s."

Hurricane landfall is difficult to predict, but, when it happens, the climate-change related impacts resulting from heavier precipitation and increased storm surge magnified by sea level rise are expected to increase the severity of damages. Additionally, a storm's status at the point of landfall may not necessarily equate to the scope of the damage: while Sandy did not make landfall as a major hurricane in 2012, it was one of the most damaging storms in U.S. history.

Question 4: Objective and unvested peer review plays a critical role in verifying the accuracy of science-based findings which serve as the basis for regulatory decisions, especially since these decisions raise the cost of energy throughout the United States. Do you agree it is critical that all information and data which underlie these findings be made publicly available and accessible so that a broad cross-section of credentialed peer reviewers and other capable investigators alike can independently verify an agency's scientific integrity?

Response:
The EPA is deeply committed to transparency. As such, the EPA posts publicly available information and data related to regulatory decisions on the public docket (www.regulations.gov). Additionally, we are working to expand the agency's existing efforts in place under the Open Government initiative https://www.whitehouse.gov/Open/ to make available the manuscripts and data supporting conclusions in the EPA-funded publications.